entitled to any exemption from such requirement; and 503 (b) (4)—all of the articles were drugs subject to 503 (b) (1), and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription"; and 505 (a)—the repackaged and relabeled *meticortelone tablets* were a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 11–26–56. Default—destruction.

DRUG FOR VETERINARY USE

**5142. Acthone gel (veterinary).** (F. D. C. No. 39929. S. No. 58–623 M.)

QUANTITY: 97 5-cc. vials at Denver, Colo.

SHIPPED: Between 9–1–56 and 9–6–56, from San Francisco, Calif., by Borden Laboratory.

LABEL IN PART: (Vial) "Borden Acthone (Veterinary) Gel * * * 40 U. S. P. Corticotropin Units."

LIBELED: 1–30–57, Dist. Colo.

CHARGE: 505 (a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 3–22–57. Default—destruction.

## DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

**5143. Herb tonics, cold salve, and laxative tablets.** (F. D. C. No. 38515. S. Nos. 14–410/1 M, 14–414 M, 14–417 M, 14–426 M, 14–470/3 M, 14–581 M, 30–148 M.)

INDICTMENT RETURNED: 3–8–56, E. Dist. Ill., against William H. Cruez, t/a East Side Herb Co., East St. Louis, Ill.

ALLEGED VIOLATION: Between 2–23–55 and 8–1–55, the defendant caused to be introduced into interstate commerce at East St. Louis, Ill., for delivery into the State of Missouri, quantities of various drugs which were labeled and misbranded as described below.

On 5–18–55, the defendant unlawfully refused entry and inspection of his establishment at East St. Louis, Ill., after having been presented by inspectors of the Food and Drug Administration with appropriate credentials and a written notice at a reasonable time, in accordance with the provisions of Section 704.

LABEL IN PART: "Herb Tonic Formula No. 1 Active Ingredients Punich, Granatum, and Pest Root"; "Herb Tonic Formula No. 3 Active Ingredients Quaking Aspen, Pride Weed, and Lucerne"; "Herb Tonic Formula No. 4 Active Ingredients Prickly Ash, Tansy Herb, Button Bush Bark and Elder Bark"; "Cold Salve" (examination showed that it contained, chiefly, petrolatum and smaller amounts of menthol and eucalyptol); and "Tablets Formula No. 556 Active Ingredients: Cascarin one-fourth grain, Aloin one-fourth grain, Podophyllin one-sixth grain, Extr. Belladonna one-eighth grain, Gingerine one-sixteenth grain. Distributed by Indiana Botanic Gardens, Hammond, Indiana."

*See also No. 5141.

CHARGE: 502 (f) (1)—the labeling of the articles failed to bear adequate directions for use in the treatment of the diseases for which the articles were recommended orally by the defendant, namely, (Formula No. 1 and Formula No. 556) ulcers, (Formula No. 3 and cold salve) arthritis, and (Formula No. 4) diabetes.

PLEA: Not guilty.

DISPOSITION: The case was tried before the court without a jury on 6–11–56. On 6–20–56, after consideration of the evidence and briefs of counsel, the court handed down its findings of fact, conclusions of law, and verdict of guilty, as reported in 144 F. Supp. 229. On 6–27–56, the court fined the defendant $2,000, sentenced him to serve 1 year and 1 day in prison, and placed him on probation for a period of 5 years, to begin upon his release from prison.

**5144. Tryptacin tablets.** (F. D. C. No. 35585. S. Nos. 19–876 L, 39–562 L, 43–165 L, 48–106 L, 64–364 L, 72–361 L.)

INDICTMENT RETURNED: 3–1–55, N. Dist. Ohio, against Rhodes Pharmacal Co., Inc., Cleveland, Ohio, J. Sanford Rose, president, and Jerome H. Rose, vice president and treasurer, of the corporation.

SHIPPED: Between 9–18–52 and 9–29–53, from Ohio to Minnesota, West Virginia, Louisiana, Washington, and California.

LABEL IN PART: (Btl.) "Tryptacin RHODES * * * Each tablet contains Aluminum Hydroxide Gel (Dried), Magnesium Trisilicate, Magnesium Oxide, Polyamine Methylene Resin, Ethyl p-Aminobenzoate (Benzocain) and water soluble Chlorophyllins in a special demulcent base."

RESULTS OF INVESTIGATION: The article was represented in its advertising for use in the treatment of stomach ulcers.

CHARGE: 502 (f) (1)—the labeling of the article failed to bear adequate directions for use since its labeling failed to state all of the conditions and diseases for which the article was intended to be used and was offered to the public in its advertising, and since the labeling of the article failed also to state the dosage and frequency and duration of administration for the treatment and prevention of such conditions and diseases.

PLEA: Guilty—by corporation; nolo contendere by individuals.

DISPOSITION: 6–29–56. Corporation fined $5,500; individuals placed on probation for 3 years.

**5145. Dextro-amphetamine sulfate tablets.** (F. D. C. No. 39204. S. Nos. 18–962 M, 19–483/4 M, 19–486/7 M, 23–854 M, 30–682 M, 31–060 M.)

INFORMATION FILED: 12–11–56, S. Dist. Ohio, against Ace Tablet Co., a partnership, Steubenville, Ohio, and Rinaldo D. Tarquinio, partner.

SHIPPED: Between 10–12–55 and 3–17–56, from Ohio to Arizona, Tennessee, and Kentucky.

LABEL IN PART: (Btl.) "Tablets Dextro Amphetamine Sulfate 5 Mg. Caution: Federal law prohibits dispensing without a prescription."

RESULTS OF INVESTIGATION: The tablets were shipped to persons who were not authorized to receive them.

CHARGE: 502 (f) (1)—the labeling of the article failed to bear adequate directions for use.

PLEA: Guilty.